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09/896,052	06/29/2001	Frank J. Bunick	MCP-281	9476

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EXAMINER	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/896,052
Filing Date: June 29, 2001
Appellant(s): BUNICK ET AL.

Timothy E. Tracy
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 09 December 2004.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 1-25 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

6,060,078	LEE	05-2000
6,139,865	FRIEND et al.	10-2000

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Lee and Friend *et al.* (U.S. Patent No. 6,139,865)

Lee teaches a chewable pharmaceutical dosage form comprising of a core containing an active ingredient, and an outer layer (See Figure 2). The dosage form demonstrates improved organoleptic properties when chewed, such as taste (See Column 1, Lines 47-52). The core may be in the form of a jelly, with the base of the jelly selected from a group that includes pectin (See Column 2, Lines 29-33). In addition, gelatin may be used in either the core or outer layer to maintain hardness and extension property in the dosage form (See Column 2, Lines 59-61). The outer layer may take a variety of forms, including hard candy (See Column 2, Lines 34-42).

Acetaminophen is listed as a possible active ingredient in the core (See Column 2, Lines 9-18). In addition, Lee contains what the examiner will interpret as an enabling disclosure of a dosage form with a unitary core (See Figure 2; and MPEP § 2125).

The Lee patent does not teach the use of ibuprofen in the disclosed dosage form.

The Friend *et al.* patent teaches taste-masked microcapsule compositions for the administration of a drug (See Abstract). Drugs to be used in the disclosed compositions include acetaminophen and ibuprofen (See Column 4, Lines 28-37). The compositions may be incorporated into a variety of dosage forms, including chewable tablets, in amounts ranging from 10% to 95% by weight of the dosage form (See Column 4, Lines 55-65; and Column 9, Line 56 to Column 10, Line 25). It is preferred that the microcapsules range in size from approximately 30 microns to 800 microns (See Column 8, Line 30-36).

It would be obvious to one of ordinary skill in the art to combine the teachings of Lee and Friend *et al.* into the objects of the instant application. Both the Lee and Friend *et al.* patents deal with the administrations of drugs in pharmaceutical compositions with improved organoleptic properties. Therefore, one of ordinary skill would be motivated to incorporate the composition disclosed in Friend *et al.* into the dosage form of Lee in order to provide a pharmaceutical dosage form wherein the active ingredient is further taste-masked without an undue delay on the release of the drug. As Friend *et al.* states that the disclosed compositions may be incorporated into chewable tablets, in the view of the examiner, this disclosure provides sufficient guidance to one of ordinary skill in the art to incorporate them into the chewable dosage form taught in Lee. As such, it is the position of the examiner that one of ordinary skill in the art could combine the disclosures of the prior art with a reasonable expectation of success.

The adjustment and optimization of parameters such as hardness of the soft core and the weight ratio of active agent particles are considered by the examiner to be well within the purview of one of ordinary skill in the art. Therefore, claim limitations drawn to such features are not considered by the examiner to impart a patentable quality unto the instantly claimed invention.

Thus, the instantly claimed invention is *prima facie* obvious.

(11) Response to Argument

In applying the prior art against the claims, what the examiner meant was that a composition is inseparable form its properties. As the examiner has shown through the collective disclosure of the prior art, the obviousness of an oral dosage form comprising a plurality of active agent particles and a brittle shell encasing the soft core has been established. It would follow then that such a dosage form arising out of the disclosure of the prior art would also have the properties of texture masking.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Although the applicant does not agree with the examiner's use of the disclosure of the Friend *et al.* patent in the prior art rejection of record, there is nothing within the language of the instantly claimed invention that specifically bars the use of the microencapsulated drug particles. In the view of the examiner, such particles may be incorporated into the dosage form of Lee,

such that the resulting dosage form would properly read on the instantly claimed invention. Despite the applicant's arguments that the Friend *et al.* patent lacks guidance as to what is meant by a "granular" particle size, Example 1 of that reference clearly states that the drug particles formed in the example are sieved through an 840 μm screen (See Column 11, Lines 64-65), which would place them within the preferred range particle sizes (See Column 8, Lines 31-36).

As mentioned above, the adjustment and optimization of parameters such as hardness of the soft core and the weight ratio of active agent particles are considered by the examiner to be well within the purview of one of ordinary skill in the art. Therefore, claim limitations drawn to such features are not considered by the examiner to impart a patentable quality unto the instantly claimed invention.

The applicant has also set forth the argument that the references are not properly combinable, due to differences in process temperatures between the two patent references. In response to these arguments, the examiner would like to point out that there is nothing in the Friend *et al.* patent that requires that the incorporation of the disclosed encapsulated drug particles into oral dosage forms takes place at the same elevated temperature (80°C) at which the particles were prepared. No such indication is given within the Friend *et al.* reference itself, where the encapsulated drug particles, prepared in a previous batch process, are used to make effervescent tablets (See Column 13, Example 4). By the applicant's admission, these particles are cooled. However, further reading will disclose that the final process temperature of the particles before filtration is 20°C, not 50°C as alleged by the applicant, before being dried at room temperature and then at reduced pressure (See Column 1, Lines 55-62). Presumably then, these particles would go on to be incorporated into oral dosage forms at around room

temperature, such as, for example, the chewable dosage form disclosed by the Lee reference.

Thus, the prior art references remain properly combinable.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Simon J. Oh
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sjo
May 16, 2005

Conferees

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